



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/740,582      | 12/19/2000  | Man C. Niu           | 13402.00004         | 6349             |

7590 11/06/2003

Charles N. Quinn  
Fox Rothschild O'Brien & Frankel, LLP  
2000 Market Street  
10th Floor  
Philadelphia, PA 19103-3291

| EXAMINER |
|----------|
|----------|

BAUM, STUART F

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1638

DATE MAILED: 11/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 09/740,582             | NIU, MAN C          |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Stuart F. Baum         | 1638                |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 July 2003 and 30 July 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16, 19-22 and 25-73 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16, 19-22, 25-32, 34-46 and 48-73 is/are rejected.
- 7) ☒ Claim(s) 33 and 47 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/19/00 and 10/1/02 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                       | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                              | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>7/2003</u> . | 6) <input type="checkbox"/> Other: _____.                                   |

### **DETAILED ACTION**

1. The amendment filed July 17, 2003 and the Declaration of Dr. Man C. Niu with accompanying remarks, both of which filed July 30, 2003, have all been entered.
2. Claims 1-16, 19-22, 25-73 are pending and are examined in the present office action.  
Claims 17-18, and 23-24 have been canceled.  
Claims 28-73 have been added.
3. Rejections and objections not set forth below are withdrawn.
4. The text of those sections of Title 35, U.S. Code not included in this office action can be found in a prior office action.

### ***Claim Objections***

5. Claims 41, 48, and 55 are objected to for being duplicate claims of 40, 47, and 54, respectively.

### ***Indefiniteness***

6. Claims 35-41, 49-65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Rejection includes dependent claims.

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim

term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term “germinating” in claims 35, 49, 56, and 61 is used by the claim to mean “that the transgenic plant somehow becomes a second generation transgenic plant”, while the accepted meaning is “the initial growth of a seed after being placed in an environment conducive for growth.” The term is indefinite because the specification does not clearly redefine the term.

#### ***Enablement***

7. Claims 1-15, 19-20, 22, 25, 28-32, 35-39, 42-46, 49-53, 56-58, 61-63, 66, 68, 70, and 72 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is maintained for the reasons of record set forth in the Official actions mailed 3/21/2002 and 1/15/2003. Applicant's arguments filed July 17, 2003 and July 30, 2003 have been fully considered but they are not persuasive.

Applicants contend that they are not required to provide an exemplary species for every aspect of the invention that might be embraced by a generic claim. Applicants disagree with the Office that the application is not enabling for isolating and purifying soy globulin mRNA. Applicants note that no specific messenger RNA was isolated (page 17, 1<sup>st</sup> paragraph). Applicants contend that 80% of the poly mRNA in soy encodes soy globulin protein and therefore it is not necessary to isolate or purify the soy mRNA (page 17, 2<sup>nd</sup> paragraph).

Art Unit: 1638

Applicants contend that the invention is not limited to the embodiments disclosed, modifications can be made, and such modifications are well within the skill of those in the art of plant molecular biology (page 18, 2<sup>nd</sup> paragraph).

The Office contends that Applicant has only isolated total poly mRNA from soy cotyledons or soy sprouts and has not isolated and purified soy globulin mRNA as is recited in the claims. Applicant is claiming all transgenic corn kernels and corn plants, as well as a method for producing transgenic plants expressing any exogenous protein but Applicant has only exemplified 2 corn varieties only expressing soy globulin protein and in addition, Applicant has disclosed that different corn varieties exhibit different competencies to being transformed, (See page 14, lines 14-24 and Table 1, in Applicant's specification). In addition, Applicant's claims are also directed to incubating any seed with mRNA. Also, Applicant has not disclosed by way of example or guidance how one skilled in the art can transform all plants by incubating a seed with mRNA. Given the arguments filed in the previous two Office actions, and the presently stated remarks, undue experimentation would be required by one skilled in the art to make and/or use the broadly claimed invention.

The Office has considered the 37 C.F.R. 1.132 Declaration of Man C. Niu and the accompanying remarks but they are not persuasive because the declaration is merely a statement by the Applicant that the protocols in the application worked. Statements in the declaration to this effect do not overcome the rejections presented in the last two office actions.

***Deposit Rejection***

8. Claims 11-16, 19-22, 25-27, 29-32, 36-39, 43-46, 50-53, 57-58, 62-63, 66, 68, 70, and 72 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is maintained for the reasons of record set forth in the Official actions mailed 3/21/2002 and 1/15/2003. Applicant's arguments filed July 17, 2003 and July 30, 2003 have been fully considered but they are not persuasive.

Applicant contends that no such assertion as to the essential or critical nature of any specific corn strain or even of corn, for practice of the invention (page 18, 1<sup>st</sup> full paragraph and page 19, 4<sup>th</sup> full paragraph). Applicant states that the corn strains 27-1 and 85089 are not the result of the transformation process but are the corn strains being transformed (page 20, top of 2<sup>nd</sup> full paragraph).

The Office contends that Applicant's claims are directed to corn strains 27-1 and 85089 and that Applicant admits that these corn varieties were chosen because they are high yielding (page 20, 2<sup>nd</sup> full paragraph). The Office acknowledges that said corn strains are not the result of a transformation process, but rather, are specific corn varieties, which according to 35 USC 112 1<sup>st</sup> paragraph, must be on deposit so as to be readily available to the public.

***Double Patenting***

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper time wise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 15-16, 19-22, 26-27, 59, 60, 64-65, 67, 69, 71, and 73 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 6, 198,025 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are obvious over the claims of Patent No. 6, 198,025 B1. Claims 1 and 2 of U.S. Patent No. 6, 198,025 B1 are drawn to a transgenic corn plant or transgenic corn kernel expressing soy globulin protein. Claims 16, 21, 26-27, 59, 60, 64-65, 67, 69, 71, and 73 of the present application are drawn to a transgenic corn plant or kernel expressing soy globulin wherein the corn plant or corn kernel is strain 27-1 or strain 85089. Although the conflicting claims are not identical, they are not patentably distinct from each other, and read on the claims of the present application.

Art Unit: 1638

10. Claims 33, and 47 are objected to for being dependent on a rejected base claim and would be allowable if re-written in independent form to include all limitations.

11. Claims 1-16, 19-22, 25-32, 34-46, and 48-73 are rejected.

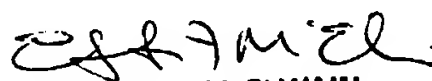
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 703-305-6997. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Stuart F. Baum Ph.D.

October 29, 2003

  
ELIZABETH F. McELWAIN  
PRIMARY EXAMINER  
GROUP 1600